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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,105

12/29/2003

Carlos Vonderwalde

3141.002C

3163

23405

7590

05/22/2008

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

05/22/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/749,105	<b>Applicant(s)</b> VONDERWALDE ET AL.	
	<b>Examiner</b> KATHLEEN SONNETT	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 80-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 80-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 80-83 were rejected only on the grounds of nonstatutory obviousness-type double patenting over US 6,929,658 in the office action mailed 8/24/2007. The rejections have been overcome by the terminal disclaimer filed on 2/19/2008. However, after further consideration, claims 80-83 have been rejected over the prior art of Buirge et al., Edwin et al., Kruse, and White as discussed in detail below.

#### ***Terminal Disclaimer***

2. The terminal disclaimer filed on 2/19/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,929,658 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 80-82** are rejected under 35 U.S.C. 103(a) as being unpatentable over Buirge et al. (US 5,693,085) in view of Edwin et al. (US 6,053,943) and Kruse (US 2,048,873). Buirge et al. discloses a method of making a stent assembly including the steps of providing a stent including a substantially tubular stent having a first and second end and at least two cover connectors associated with the stent body, each of the cover connectors including at least one penetrating element (col. 11, ll. 30-35), contacting the graft material with the surface of the stent so that a first edge is in proximity to a second edge of the stent so as to form a tubular stent

Art Unit: 3731

cover (fig. 18; col. 12, ll. 29-34), and piercing the graft with the penetrating element so that the elements penetrate through the graft so as to secure the graft to the stent. Buirge et al. fails to disclose that, when the sheet is rolled up, the first and second edges of the sheet substantially abut, wherein a first penetrating element penetrates through the sheet in proximity of the first edge and a second penetrating element penetrates in proximity of the second edge.

5. However, Edwin et al. discloses that it is old and well known to wrap around a graft member around a support structure so that the edges of the sheet abut one another (col. 12, ll. 66-col. 13, ll. 7; see also barbs 62 which penetrate graft material). Employing such a configuration on the device of Buirge et al. would have been obvious to one skilled in the art in order to provide total coverage of the stent with the graft while minimizing the amount of material needed for the graft as compared to an overlapping configuration. Regarding the location of penetrating members of Buirge et al. near the first and second edge, it would have been obvious to one skilled in the art to have placed the cover connectors of Buirge et al. so that a first penetrating element is in proximity to the first edge and a second penetrating element is in proximity to the second edge because the area around the seam is vulnerable to peeling. Furthermore, such a configuration of a rectangular sheet formed into rolled sheet wherein abutting sides are connected with penetrating members attached on either side of the seam is well known as demonstrated by Kruse (fig. 3). It would have been obvious to one skilled in the art to have modified the method of Buirge et al. to include wrapping the graft around the stent such that the two edges are in abutting contact taught by Edwin et al. as well as providing penetrating members in proximity to both edges of the rolled graft in order to ensure that the graft does not peel away from the stent along its seam.

6. Regarding claim 81, the sheet may be folded such that it is in contact with an inner surface of the stent body (fig. 14 of Buirge et al.).

Art Unit: 3731

7. **Claim 83** is rejected under 35 U.S.C. 103(a) as being unpatentable over Buirge et al. in view of Edwin et al. and Kruse, as applied to claim 80 above, and further in view of White (US 5,782,904). Modified Buirge et al. discloses the method substantially as stated above but fails to expressly disclose bending a portion of the penetrating elements penetrating through the sheet over the sheet.

8. White discloses that it is old and well known in the art to bend penetrating members used to connect a graft to a stent in order to have penetrating members project in opposite longitudinal directions along the graft body. This assists in preventing longitudinal movement of the graft along the vessel in either direction (col. 3 ll. 55-61). It would have been obvious to one skilled in the art to modify the method of Buirge et al. to include the step of bending a portion of the penetrating elements penetrating through the sheet over the sheet as made obvious by White et al. in order to gain the advantage of preventing longitudinal movement of the graft along the vessel in either direction.

### ***Response to Arguments***

9. Applicant's arguments with respect to claims 80-83 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 5/12/2008

/Michael G Mendoza/

Supervisory Patent Examiner, Art Unit 3734